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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/728,072

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Ron Heil

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/728,072	Applicant(s) HEIL ET AL.	
	Examiner MICHAEL KAHELIN	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 25-66 is/are pending in the application.
- 4a) Of the above claim(s) 33-47 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18-23 and 25-32 is/are allowed.
- 6) ☒ Claim(s) 1-17 and 48-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20080828</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-17, 50, 52, and 54-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-17, 50, 52, and 55-66 recite a lead body with the PVDF sonophoresis arrangement. Although the examiner was able to find support for the PVDF arrangement for the can (Fig. 5B and accompanying description), he was unable to find support for the configuration applied to the lead body or combination lead body and can. This appears to be an unsupported mixing of embodiments. In regards to claims 14 and 54, the examiner was unable to find support for an embodiment that is both rigid and malleable as claimed in claims 14 and 54. This appears to be an unsupported mixing of embodiments. Appropriate correction is required.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-17, 48-54, 60, and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

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subject matter which applicant regards as the invention. In regards to claims 1, 14, 48, 52, and 54, it is unclear how the lead body can be both rigid and malleable. Due to the dependence of claims 14 and 54 on claims 1 and 48, respectively, "rigid" includes the malleable embodiment. In regards to claims 15, 17, 60, and 62, it is unclear how a DC current provides sonophoresis due to the requirement of an oscillating driving force for sonophoresis. This appears to be in reference to the disclosed DC current provided for *electrophoresis*. Appropriate correction is required. In regards to claim 52, the PVDF layer and conducting surface are lacking antecedent basis.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 48, 49, and 53 are rejected under 35 U.S.C. 102(b) as anticipated by Darvish et al. (US 7,190,997, hereinafter "Darvish") or, in the alternative, under 35 U.S.C. 103(a) as obvious over Darvish in view of Bardy et al. (US 2002/0035376, hereinafter "Bardy").

9. In regards to claims 48 and 49, Darvish discloses a lead body comprising a rigid elongated support structure the stabilizes and maintains spacing between the electrode and can (col. 17, line 15; as the lead is grasped to the tissue, it is rigid; alternatively, due to the conductive metal and insulative coating construction, the lead has some amount of resistance to bending, thus "rigid" compared to, e.g., an insulative coating without the conductor); a cardiac electrode (col. 17, lines 3-24); an implantable can; one or more conductors (col. 12, line 37-col. 13, line 35); a pharmacological agent provided along at least a portion of the exterior surface of the lead; and a means for impelling the agent into tissue using electrophoresis (col. 17, lines 3-24). In the alternative, Darvish discloses the essential features of the claimed invention except for a rigid elongated support structure. Bardy teaches a similar implanted cardiac device having a rigid elongated support structure (Fig. 14 and pars. 0045, 0058, and 0063-0067) to provide the predictable results of a comfortable canister that conforms to the unique shape of a patient's ribs. Therefore, it would have been obvious to one having ordinary skill in the

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art at the time the invention was made to modify Darvish's invention by providing a rigid elongated support structure to provide the predictable results of a comfortable canister that conforms to the unique shape of a patient's ribs.

10. In regards to claim 53, Darvish discloses facilitating delivery after cardiac stimulation therapy (col. 12, lines 50-56; during the "refractory state" in a pacemaker-augmented heart; alternatively, continuous application of phoresis current meets the claim language).

11. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Darvish in view of Bardy. Darvish discloses the essential features of the claimed invention except for a can having a unitary structure having an arcuate shape. Bardy teaches a can having an arcuate shape (Figs. 13-15) to provide the predictable results of a comfortable canister that conforms to the unique shape of a patient's ribs. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Darvish's invention by providing a can having an arcuate shape to provide the predictable results of a comfortable canister that conforms to the unique shape of a patient's ribs.

12. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Darvish (or Darvish in view of Bardy). Darvish (or Darvish in view of Bardy) discloses the essential features of the claimed invention except for an elongated support structure having a mechanical memory. It is well known in the implantable lead arts to provide support structures having a mechanical memory to provide the predictable results of ensuring proper placement of leads. Therefore, it would have been obvious to one

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having ordinary skill in the art at the time the invention was made to provide Darvish's (or Darvish in view of Bardy's) invention with a support structure having a mechanical memory to provide the predictable results of ensuring proper placement of the lead electrodes.

Allowable Subject Matter

13. Claims 18-23 and 25-32 are allowed.
14. Claims 50 and 52 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1st and 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
15. Claims 1-17 and 55-66 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 1st and 2nd paragraph, set forth in this Office action.

Response to Arguments

16. Applicant's arguments with respect to claims 1-23, 25-32, and 48-66 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rebell (US 4,917,104) is one of many teachings of a shape-memory lead.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762

/Angela D Sykes/
Supervisory Patent Examiner, Art Unit 3762